MAY 3 1 2013

BLUE BELT TECHNOLOGIES, INC

510(k) Summary

510(k) SPONSOR: Blue Belt Technologies, Incorporated
2828 Liberty Avenue, Suite 100
Pittsburgh, PA 15222

DATE 510(K) Summary was Prepared: 4-9-13

CONTACT PERSON:

Company Representative: Richard Confer
Title: Vice President of Regulatory Affairs and Quality Assurance
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TRADE NAME: STRIDE Unicondylar Knee

COMMON NAME: Unicompartmental Knee, Unicondylar Knee

CLASSIFICATION: 21 CFR 888.3520
CLASS: Class II
PRODUCT CODE: HSX
PANEL: Orthopedic

PREDICATE DEVICES: The predicate devices for the STRIDE Unicondylar Knee are the Zimmer® Unicompartmental Knee System, K033363 (cleared 1/16/2004); and the MAKO Surgical Corporation Unicondylar Knee Implant System III, K082081 (cleared 8/15/2008).

DEVICE DESCRIPTION: The STRIDE Unicondylar Knee device is a unicompartmental prosthetic implant that resurfaces one femoral condyle, and one side of the tibial plateau. The femoral component is made of cobalt chrome and the tibial component is made of titanium with a UHMWPE insert that snaps into place. The device is non-constrained; the articulating surface of the UHMWPE insert is flat and joint stability is maintained by ligaments and other soft tissue surrounding the knee.

INDICATIONS FOR USE: The STRIDE Unicondylar Knee devices are indicated for patients with:

- Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
- Previous tibial condyle or plateau fractures with loss of anatomy or function.
- Varus or valgus deformities.
- Revision of previous arthroplasty procedures.

These devices are indicated for cemented use only.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The STRIDE Unicondylar Knee is substantially equivalent to the Zimmer Unicompartmental Knee System and the MAKO Surgical Corporation Unicondylar Knee Implant System III. All three of these devices are non-constrained unicondylar knee prostheses made of similar materials. The manufacturing and sterilization methods are equivalent. These devices are approximately the same geometrically, and indications for use are equivalent. Each of these devices is indicated for cemented use only. A comparison of the STRIDE Unicondylar Knee to the Zimmer Unicompartmental Knee and the MAKO Surgical Corporation Unicondylar Knee Implant System III indicates that the subject device is substantially equivalent to the predicate devices:

Characteristics	STRIDE Unicondylar Knee (Subject Device)	Zimmer Unicompartmental Knee (ZUK)	MAKO Unicondylar Knee Implant System III
Intended Use	These devices are intended to be used in unicondylar knee patients meeting the indications for use.	These devices are intended for patients with [see the indications for use below]:	Mako Surgical Corp. Unicondylar Knee Implant System III components are intended for use in unicompartmental knee arthroplasty as a result of [see the indications for use below]:
Indications	Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis. Previous tibial condyle or plateau fractures with loss of anatomy or function. Varus or valgus deformities. Revision of previous arthroplasty procedures. These devices are indicated for cemented use only.	Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis. Previous tibial condyle or plateau fractures with loss of anatomy or function. Varus or valgus deformities. Revision of previous arthroplasty procedures. These devices are indicated for cemented use only. The ZUK unicompartmental knee is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.	Moderately disabling joint disease of the knee resulting from painful osteo- or post-traumatic arthritis. As an alternative to tibial osteotomy in patients with unicompartmental Osteoarthritis. Revision of previous unsuccessful unicompartmental knee replacement. These devices are intended for cemented use only.
Materials	Femoral: CoCrMo Tibial Plate: Titanium Tibial Insert: UHMWPE	Femoral: CoCrMo Tibial Plate: Titanium Tibial Insert: UHMWPE	Femoral: CoCrMo Tibial Plate: Titanium Tibial Insert: UHMWPE
Sterilization and Packaging	Gamma, metal components; Gamma (UHMWPE); All components are supplied in double sealed containers maintaining double sterile barriers. Sterilization parameters are designed to meet SAL 10^{-6}, and a shelf life of 2 years	Gamma, metal components; Gamma, (UHMWPE); All components are supplied in double sealed containers maintaining double sterile barriers	Gamma, metal components; Gamma, (UHMWPE) All components are supplied in double sealed containers maintaining double sterile barriers
Designs	Curved back femoral component, 1 posterior facet Onlay tibial plate Fixed non-constrained insert	Faceted back femoral. component, 3 facets Onlay tibial plate Fixed non-constrained insert	Curved back femoral. component, 1 posterior facet Onlay and inlay tibial plates Fixed non-constrained insert

The engineering analysis and non-clinical (bench) testing of the Stride Unicondylar Knee and the predicate included:

- Finite element analysis (FEA) comparing load stresses at 0, 15, 20, 60, 90 and 120 and 155 degrees of flexion
- FEA Stress Analysis Comparison at +/- 10 degrees of varus/valgus and 0, 15 and 60 degrees of flexion
- Contact pressure bench testing to ASTM F2083-10 for Stride
- Engineering analysis for Stride tibial component fatigue
- Tibial tray and insert interlocking strength and force analysis
- Range of motion analysis
- Biocompatibility of materials analysis per ISO 10993
- Sterilization to SAL of 10^{-6}
- Packaging and shelf life analysis

Analysis and testing results demonstrated that the subject device meets its design specifications.

SUMMARY AND CONCLUSIONS:

The STRIDE Unicondylar Knee was designed to utilize materials, geometry, and manufacturing methods similar to the predicate devices and which are currently used in clinical practice. The similarity between the subject device and the predicate devices with respect to indications, design, materials, packaging and sterilization methods, combined with FEA and bench test results, and an FMEA hazard analysis, identified no new hazards associated with the STRIDE Unicondylar Knee.

The primary differences are:

- The STRIDE Unicondylar Knee tibial plate is offered in more sizes than the individual predicates, but covers the same ranges as the combined predicate tibial plate offering.
- The Stride has differences in femoral component rear surface geometry than the predicate devices.

Test results and comparative performance data for the STRIDE and its predicate unicondylar implants indicate that these differences do not present any new issues of safety of effectiveness as compared to the predicates.

Therefore, based on the above analysis and data presented in this submission, a finding of substantial equivalence with the predicate devices is justified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2013

Blue Belt Technologies, Incorporated
% Mr. Richard Confer
Vice President of Regulatory Affairs and Quality Assurance
2828 Liberty Avenue, Suite 100
Pittsburgh, Pennsylvania 15222

Re: K123380
Trade/Device Name: Stride Unicondylar Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: May 21, 2013
Received: May 28, 2013

Dear Mr. Confer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): N/A K123380

Device Name: The STRIDE Unicondylar Knee

Indications For Use:

The STRIDE Unicondylar Knee devices are indicated for patients with:

- Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
- Previous tibial condyle or plateau fractures with loss of anatomy or function.
- Varus or valgus deformities.
- Revision of previous arthroplasty procedures.

These devices are indicated for cemented use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices